# Government Issues

# FDA REGULATIONS - TOPLINE:

As Of May 7, 1997

0887 T98TS

## Status of FDA Regulations of Tobacco Products After April 25, 1997 Court Ruling on Summary Judgment

- I. COURT RULED THAT FDA REGULATIONS WHICH WENT INTO EFFECT ON FEBRUARY 28, 1997 REMAIN IN EFFECT PENDING APPEAL.
  - \* Regulations which went into effect February 28, 1997, are those which:
    - \* Prohibit sale of tobacco products to individuals under the age of 18;
    - \* Require retailers to verify a purchaser's age by photographic identification.

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## Status of FDA Regulations of Tobacco Products After April 25, 1997 Court Ruling on Summary Judgment (continued)

- II. COURT RULED THAT FDA DOES NOT HAVE THE AUTHORITY TO REGULATE TOBACCO ADVERSTISING AND PROMOTION.
  - \* Regulations which restrict promotion and advertising defined as those which:
    - Limit advertising to black & white text-only format;
    - Restrict trade or brand name of tobacco products;
    - Prohibit sale or distribution of brand identified promotional non-tobacco items such as hats and tee-shirts;
    - Prohibit use of brand name of tobacco products to sponsor entries, teams, sporting and other events.

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#### Status of FDA Regulations of Tobacco Products After April 25, 1997 Court Ruling on Summary Judgment (continued)

- III. COURT LET STAND FDA ACCESS RESTRICTION REGULATIONS AND PACKAGE LABEL REGULATIONS, **BUT RULED THAT THE FDA CANNOT IMPLEMENT ANY REGULATIONS SCHEDULED TO GO INTO EFFECT ON AUGUST 28, 1997** (INCLUDING ACCESS RESTRICTION AND PACKAGE LABEL REGULATIONS) PENDING FURTHER ORDERS BY THE COURT.
  - \* Access restrictions (scheduled to go into effect on August 28, 1997) defined as those which:
    - Prohibit the sale of tobacco products through vending machines and self service displays except in facilities where individuals under the age of 18 are not permitted;
    - Prohibit distribution of free samples; and
    - Prohibit the sale of cigarette packages containing fewer than 20 cigarettes.

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## Status of FDA Regulations of Tobacco Products After April 25, 1997 Court Ruling on Summary Judgment (continued)

- \* Package label regulations defined as those regulations which require tobacco product packages to bear the established name of the product and statement of intended use.
- IV. CIGARETTE MANUFACTURERS AND THE FDA HAVE FILED PETITIONS TO APPEAL. THE APPEALS PROCESS COULD TAKE YEARS AND ULTIMATELY MAY RESULT IN A TRIAL ON THE ISSUE OF WHETHER THE FDA HAS JURISDICTION OVER CIGARETTES AS CUSTOMARILY MARKETED.

AS FURTHER DEVELOPMENTS OCCUR WE WILL ADVISE YOU.

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